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APPLICATION NO	). F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,650		07/11/2000	Kenneth F. Buechler	071949-1307	9972
30542	7590	02/07/2006		EXAM	INER
FOLEY & P.O. BOX	LARDNI	ER LLP	ALEXANDER, LYLE		
SAN DIEGO, CA 92138-0278				ART UNIT	PAPER NUMBER
	•			1742	***

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.	Applicant(s)					
		09/613,650	BUECHLER, KENNETH F.					
		Examiner	Art Unit					
		Lyle A. Alexander	1743					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
WHIC - Exte afte - If NO - Failu Any	CHEVER IS LONGER, FROM THE MAILING DA ensions of time may be available under the provisions of 37 CFR 1.13 r SIX (6) MONTHS from the mailing date of this communication. Depriod for reply is specified above, the maximum statutory period we use to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply b rill apply and will expire SIX (6) MONTHS f cause the application to become ABANDO	ION. e timely filed  rom the mailing date of this communication.  DNED (35 U.S.C. § 133).					
Status	•							
1)🛛	Responsive to communication(s) filed on 23 Ja	nuary 2006.						
2a)[		action is non-final.						
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11	, 453 O.G. 213.					
Disposit	ion of Claims							
4)🖂	4)⊠ Claim(s) <u>74-84 and 92-100</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)[	5) Claim(s) is/are allowed.							
6)⊠	)⊠ Claim(s) <u>74-84 and 92-100</u> is/are rejected.							
7)	Claim(s) is/are objected to.							
8)	Claim(s) are subject to restriction and/or	election requirement.						
Applicat	ion Papers							
9)[	The specification is objected to by the Examiner	·.						
	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	The oath or declaration is objected to by the Ex-	aminer. Note the attached Off	ice Action or form PTO-152.					
Priority (	under 35 U.S.C. § 119							
12)	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119	)(a)-(d) or (f).					
	☐ All b)☐ Some * c)☐ None of:	, ,	(-) (-)					
	1. Certified copies of the priority documents	have been received.						
	2. Certified copies of the priority documents have been received in Application No							
	3. Copies of the certified copies of the priority documents have been received in this National Stage							
	application from the International Bureau (PCT Rule 17.2(a)).							
* 5	* See the attached detailed Office action for a list of the certified copies not received.							
Attachmen	• •	🗖						
_	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summ Paper No(s)/Mai						
3) 🔲 Infori	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) D Notice of Informa	al Patent Application (PTO-152)					
Pape	r No(s)/Mail Date	6)						

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In response to Applicants' 1/23/06 terminal disclaimers, the Office updated the search and will make the following grounds of rejections.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 81 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are not clear if a new textured surface other than that claimed in the independent claim is intended. For the purposes of examination, it will be assumed the textured surface of the independent claim is intended. Clarification could be achieved by "said textured surface".

#### Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 74-81 and 92-99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Stocker (USP 4,647,543).

Stocker teaches a device for immunological testing of immobilized samples.

Figure 6(a) a plate(2) comprising supports(1a) within a hydrophilic area(3) for sample capture and a surrounding hydrophobic area(4). This has been read on the claimed hydrophilic/capture zones and adjacent hydrophobic zones. Support(1a) has been read on the claimed particles that immobilize the sample. Column 5 lines 59+ and claim 8

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teach the surface is not flat and has "depressions" where the sample can be trapped.

This has been read on the claimed "textured surface".

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 82 and 100 rejected under 35 U.S.C. 103(a) as being unpatentable over Stocker.

See Stocker supra.

Stocker is silent to the material of construction of particles.

The Court decided In re Leshin, (125 USPQ 416) the selection of a material of construction based upon its "suitability of intended use, would be entirely obvious". The claimed latex, ziconia, alumina, titanium, etc. particles are all well known for their inertness, availability and long track record of use with immunological materials. It would have been within the skill of the art to modify Stocker and use any one of the claimed latex, ziconia, alumina, titanium, etc. particles for the above advantages and as selection of a material based upon its suitability of intended use.

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74-84 and 92-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,458,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims "at least one zone" to bind an analyte and hydrophilic/hydrophobic regions to direct the fluid.

## Response to Arguments

The Office has reconsidered Applicant's arguments filed 8/9/05 and has deemed they are not persuasive.

Applicants' argued Stocker teaches immobilized particles and not the claimed immobilized receptors. The Office maintains the taught particles include receptors and are properly read on the instant claims.

Applicants' state even though they do not agree with the application of Stocker, to further the prosecution, size limitations of the particles have been added to unequivocally define over Stocker. The Office notes the instant claim language only specifies the particle size in the alternative (e.g. or immobilized on particles immobilized to said surface, wherein the particle size range is from 1nm to 5 nm..."). The Office has

read claims as only requiring "each said capture zone comprising receptors immobilized

to said surface "which does not carry the particle size limitations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander Primary Examiner Art Unit 1743